PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
KRISTINA M. GRASSO
KRISTINA M. GRASSO, ESQ. PLLC
P.O. BOX 162
MILFORD, NH 03055

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference FALCM009-PCT	Date of mailing *(day/month/year)* **FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US 09/49374	International filing date *(day/month/year)* 01 July 2009 (01.07.2009)
Applicant FALLON, JOAN M.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 8270

   For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/220 (January 2004)

(See notes on accompanying sheet)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference FALCM009-PCT	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US 09/49374	International filing date *(day/month/year)* 01 July 2009 (01.07.2009)	(Earliest) Priority Date *(day/month/year)* 01 July 2008 (01.07.2008)
Applicant FALLON, JOAN M.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language**, the international search was carried out on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

   b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

   c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☐ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

   ☒ the text is approved as submitted by the applicant.

   ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

   ☒ the text is approved as submitted by the applicant.

   ☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

   a. the figure of the **drawings** to be published with the abstract is Figure No. _____

   ☐ as suggested by the applicant.

   ☐ as selected by this Authority, because the applicant failed to suggest a figure.

   ☐ as selected by this Authority, because this figure better characterizes the invention.

   b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 09/49374

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61K 38/43; A61K 38/16; C12Q 1/25 (2009.01)
USPC - 424/94.64; 435/4
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC - A61K 38/43; A61K 38/16; C12Q 1/25 (2009.01)
USPC - 424/94.64; 435/4

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
IPC - A61K 38/16; A61K 38/43; A61K 38/48; C12Q 1/00; C12Q 1/25 (Words only)
USPC - 424/94.64; 435/4 (Words only)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WEST (PGPB, USPT, USOC, EPAB, JPAB); Google
Pharmaceutical, amylase, chymotrypsin, trypsin, lipase, papain, papaya, Alzheimer's, bipolar, obsessive compulsive, oppositional defiant, symptoms, and USP

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2007/0053895 A1 (Fallon) 08 March 2007 (08.03.2007); especially para [0002], [0016], [0025]-[0028], [0037]-[0040], [0044]-[0045] and [0054]-[0057]	1, 3-12, 19 and 32-36 --- 2, 13-18, 20-31, 37-60
Y	Darman, "An Introduction To Alternative Medicine For Psychiatric Conditions" [online], 22 October 2007 (22.10.2007) [retrieved on 18.09.2009], retrieved from: http://web.archive.org/web/20071022104238/http://alt-therapies4bipolar.info/ortho.html; especially pg 1 para 4 to pg 2 para 1, pg 5 para 4 and pg 8 para 4	2, 13-18, 20-31, 37-60
Y	The Alzheimer's Association, "Basics of Alzheimer's Disease" [online], 2005 [retrieved on 18.09.2009], retrieved from: http://www.alz.org/national/documents/brochure_basicsofalz_low.pdf; especially pg 2 para 1, pg 6 col 2 para 1 and 5, pg 7 col 1 para 1 and 3, and pg 7 col 2 para 3	13 and 52
Y	Mayo Clinic staff, "Bipolar disorder" [online], 04 January 2008 (04.01.2008) [retrieved on 18.09.2009], retrieved from: http://www.mayoclinic.com/health/bipolardisorder/DS00356/DSECTION=symptoms; especially pg 1 para 3 and pg 2 para 1 to pg 3 para 1	14-15 and 53-54

☒ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 September 2009 (18.09.2009)	25 SEP 2009
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 09/49374

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	Mayo Clinic staff, "Obsessive-compulsive disorder" [online], 21 December 2006 (21.12.2006) [retrieved on 18.09.2009], retrieved from: http://www.preferredalternatives.org/lat/Wellness Library/Anxiety& Panic Disorders/Obsessive-Compulsive Disorder/Obsessive-Compulsive Disorder - Mayo clinic.pdf; especially pg 2 para 2 and pg 2 para 5 to pg 3 para 1	16-17 and 55-56
Y	Mayo Clinic staff, "Oppositional defiant disorder" [online], 19 December 2007 (19.12.2007) [retrieved on 18.09.2009], retrieved from: http://www.mayoclinic.com/health/oppositional-defiant -disorder/DS00630/DSECTION=symptoms; especially pg 2 para 3 and pg 3 para 1	18 and 57

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: KRISTINA M. GRASSO
KRISTINA M. GRASSO, ESQ. PLLC
P.O. BOX 162
MILFORD, NH 03055

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	25 SEP 2009
Applicant's or agent's file reference FALCM009-PCT	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 09/49374	01 July 2009 (01.07.2009)	01 July 2008 (01.07.2008)

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61K 38/43; A61K 38/16; C12Q 1/25 (2009.01)
USPC - 424/94.64; 435/4

Applicant FALLON, JOAN M.

1. This opinion contains indications relating to the following items:

- [X] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV Lack of unity of invention
- [X] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [ ] Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	18 September 2009 (18.09.2009)	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 09/49374

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:

   a. (means)

      ☐ on paper

      ☐ in electronic form

   b. (time)

      ☐ in the international application as filed

      ☐ together with the international application in electronic form

      ☐ subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 09/49374

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	2, 13-18, 20-31 and 37-60	YES
	Claims	1, 3-12, 19 and 32-36	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-60	NO
Industrial applicability (IA)	Claims	1-60	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1, 3-12, 19, 32-36 lack novelty under PCT Article 33(2) as being anticipated by US 2007/0053895 A1 (Fallon)

As per claims 1 and 4, Fallon discloses a method for treating a patient with one or more symptoms of a disorder (para [0025], "improve a symptom of the disorder") associated with gastrointestinal dysfunction (para [0037], disclosing wherein "dysautonomic disorders such as Parkinson's disease" can cause "partial paresis of the gastrointestinal tract," which will "preclude the proper formation and/or release of... pancreatic enzymes such as chymotrypsin") comprising administering to the patient a therapeutically effective amount of a pharmaceutical composition comprising one or more digestive enzymes, more specifically one or more pancreatic enzymes (para [0025], "administering an effective amount of digestive/pancreatic enzymes to an individual having the disorder in order to improve a symptom of the disorder").

As per claim 3, Fallon discloses claim 1 and further discloses wherein the one or more digestive enzymes comprise one or more enzymes selected from the group consisting of proteases (para [0038], "therapeutically effective amount of a protease"), amylases (para [0038], "therapeutically effective amount of... an amylase"), papaya (para [0038], "The formulation may include... papaya"), papain (para [0038], "The formulation may include... papain"), and lipases (para [0038], "therapeutically effective amount of... a lipase").

As per claim 5, Fallon discloses claim 3 and further discloses wherein wherein the proteases comprise chymotrypsin and trypsin (para [0038], "The formulation may include... chymotrypsin, trypsin").

As per claims 6 and 7, Fallon discloses claim 1 and further discloses wherein the one or more digestive enzymes are, independently, derived from an animal source such as a pig, a microbial source, or a plant source, or are synthetically prepared (para [0044], "enzymes can be in the form of animal or plant derivatives, natural or synthetic").

As per claim 8, Fallon discloses claim 1 and further discloses wherein the pharmaceutical composition comprises at least one amylase (para [0038], "therapeutically effective amount of... an amylase"), a mixture of proteases comprising chymotrypsin and trypsin (para [0038], "The formulation may include... chymotrypsin, trypsin"), at least one lipase (para [0038], "therapeutically effective amount of... a lipase"), and papain (para [0038], "The formulation may include... papain").

As per claim 9, Fallon discloses claim 8 and further discloses wherein the pharmaceutical composition further comprises papaya (para [0038], "The formulation may include... papaya").

As per claim 10, Fallon discloses claim 1 and further discloses wherein the pharmaceutical composition comprises (para [0039], "dosage formulations may be as follows"): amylases from about 10,000 to about 60,000 U.S.P (para [0040], "Amylase, 10,000-70,000 USP units/mg"); proteases from about 10,000 to about 70,000 U.S.P (para [0040], "Protease 10,000-80,000 USP units/mg"); lipases from about 4,000 to about 30,000 U.S.P (para [0040], "Lipase 4,000-40,000 USP units/mg"); chymotrypsin from about 2 to about 5 mg (para [0040], "Chymotrypsin 2-5 mg"); trypsin from about 60 to about 100 mg (para [0040], "Trypsin 60-100 mg"); papain from about 3,000 to about 10,000 USP units (para [0040], "Papain 3,000-30,000 USP units/mg"); and papaya from about 30 to about 60 mg (para [0040], "Papaya 30-500 mg").

As per claims 11 and 12, Fallon discloses claim 1 and further discloses wherein the pharmaceutical composition comprises at least one protease (para [0038], "therapeutically effective amount of a protease") and at least one lipase (para [0038], "therapeutically effective amount of... a lipase"); and wherein the ratio of total proteases to total lipases ranges from about 1:1 to about 20:1, more specifically from about 4:1 to about 10:1 (para [0040], disclosing a protease range of "10,000-80,000 USP units/mg" and a lipase range of "4,000-40,000 USP units/mg", thereby disclosing a protease/lipase ratio in the range of about 1:4 to about 20:1).

-- Please See Supplemental Box --

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Box V.2. Citations and explanations:

As per claim 19, Fallon discloses claim 1 and further discloses wherein the pharmaceutical composition is a dosage formulation selected from the group consisting of tablets, capsules and sprinkles (para [0045], "dosages were administered in the form of encapsulated tablets, capsules, and sprinkles").

As per claims 32 and 33, Fallon discloses a pharmaceutical composition comprising one or more digestive enzymes (para [0028], "a formulation of digestive enzymes/pancreatic enzymes"), wherein the one or more digestive enzymes comprise at least one lipase (para [0038], "therapeutically effective amount of... a lipase") and at least one protease (para [0038], "therapeutically effective amount of a protease"), and wherein the ratio of total proteases to total lipases ranges from about 1:1 to about 20:1, more specifically from about 4:1 to about 10:1 (para [0040], disclosing a protease range of "10,000-80,000 USP units/mg" and a lipase range of "4,000-40,000 USP units/mg", thereby disclosing a protease/lipase ratio in the range of about 1:4 to about 20:1).

As per claim 34, Fallon discloses a pharmaceutical composition (para [0028], "a formulation of digestive enzymes/pancreatic enzymes") comprising at least one amylase (para [0038], "therapeutically effective amount of... an amylase"), a mixture of proteases comprising chymotrypsin and trypsin (para [0038], "The formulation may include... chymotrypsin, trypsin"), at least one lipase (para [0038], "therapeutically effective amount of... a lipase"), and papain (para [0038], "The formulation may include... papain").

As per claim 35, Fallon discloses claim 34 and further discloses wherein the pharmaceutical composition further comprises papaya (para [0038], "The formulation may include... papaya").

As per claim 36, Fallon discloses claim 34 and further discloses wherein the ratio of total proteases to total lipases ranges from about 1:1 to about 20: 1 (para [0040], disclosing a protease range of "10,000-80,000 USP units/mg" and a lipase range of "4,000-40,000 USP units/mg", thereby disclosing a protease/lipase ratio in the range of about 1:4 to about 20:1).

Claims 2, 20-31, 37-51 and 58-60 lack an inventive step under PCT Article 33(3) as being obvious over Fallon in view of the article titled "An Introduction To Alternative Medicine For Psychiatric Conditions" by Darman

As per claim 2, Fallon teaches claim 1 but fails to teach the further claim limitations taught by Darman, namely wherein the disorder is a neurological or mental health disorder selected from the group consisting of bipolar disorder and obsessive compulsive disorder (pg 1 para 4 to pg 2 para 1, teaching wherein "illnesses... considered psychiatric in nature," such as "obsessive compulsive disorder" and "bipolar disorder" can be caused by issues with "the pancreas, in regard to both it's insulin production and digestive enzyme production"). It would have been obvious to one with ordinary skill in the art to treat the disorders taught in Darman with the digestive enzyme formulation taught in Fallon because Darman teaches that "mental illnesses" such as bipolar disorder and OCD, can be affected by problems with the pancreas, especially "in regard to both it's insulin production and digestive enzyme production" (pg 2 para 1); that "gut toxins, and the issues that cause them, can cause severe psychiatric symptoms" (pg 5 para 4); and that mental illnesses such as "bipolar disorder" can be treated by using "digestive enzymes" to "fix the gut... to digest and absorb" properly (pg 8 para 4). Fallon also teaches that the digestive enzyme formulation can be used to "ameliorate dysautonomic symptoms" such as "abnormality of protein digestion and/or pancreatic dysfunction" caused by "partial paresis of the gastrointestinal tract" (para[0037]). Using the enzyme formulation to treat the disorders taught in Darman therefore increases the effectiveness and marketability of the product for treating these mental illnesses.

As per claim 20, Fallon teaches a method of diagnosing a patient (para [0002], "method for diagnosing individuals") comprising obtaining a fecal sample from the patient (para [0002], "analyzing a stool sample of an individual"); determining a level of chymotrypsin present in the fecal sample (para [0027], "measuring a quantitative level of a pancreatic enzyme, such as chymotrypsin, present in the stool sample"); and diagnosing the patient (para [0024], teaching "determining whether an individual has" a particular disorder) as having a disorder associated with gastrointestinal dysfunction (para [0037], disclosing wherein "dysautonomic disorders such as Parkinson's disease" can cause "partial paresis of the gastrointestinal tract," which will "preclude the proper formation and/or release of... pancreatic enzymes such as chymotrypsin") if the determined fecal chymotrypsin level is 8.4 U/gram or less (para [0054], "Normal levels of chymotrypsin are considered be greater than 8.4 U/gram") and the patient exhibits at least one symptom associated with the disorder (para [0045], "Physical symptoms of the disease... were monitored and measured").

Fallon fails to teach the further claim limitations taught by Darman, namely wherein the disorder is a neurological or mental health disorder selected from the group consisting of bipolar disorder and obsessive compulsive disorder (pg 1 para 4 to pg 2 para 1, teaching wherein "illnesses... considered psychiatric in nature," such as "obsessive compulsive disorder" and "bipolar disorder" can be caused by issues with "the pancreas, in regard to both its insulin production and digestive enzyme production").

It would have been obvious to one with ordinary skill in the art to treat the disorders taught in Darman with the digestive enzyme formulation taught in Fallon because Darman teaches that "mental illnesses" such as bipolar disorder and OCD, can be affected by problems with the pancreas, especially "in regard to both it's insulin production and digestive enzyme production" (pg 2 para 1); that "gut toxins, and the issues that cause them, can cause severe psychiatric symptoms" (pg 5 para 4); and that mental illnesses such as "bipolar disorder" can be treated by using "digestive enzymes" to "fix the gut... to digest and absorb" properly (pg 8 para 4). Fallon also teaches that the digestive enzyme formulation can be used to "ameliorate dysautonomic symptoms" such as "abnormality of protein digestion and/or pancreatic dysfunction" caused by "partial paresis of the gastrointestinal tract." Using the enzyme formulation to treat the disorders taught in Darman therefore increases the effectiveness and marketability of the product for treating these mental illnesses.

-- Please See Supplemental Box 2 --

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Supplemental Box 1

As per claim 21, Fallon and Darman teach claim 20 and Fallon further teaches wherein the fecal chymotrypsin level is between 8.4 and 4.2 U/gram (para [0054], teaching wherein "Normal levels of chymotrypsin are considered be greater than 8.4 U/gram" and wherein "less than 4.2 U/gram" can indicate severe pancreatic disfunction).

As per claim 22, Fallon and Darman teach claim 20 and Fallon further teaches wherein the fecal chymotrypsin level is less than 4.2 U/gram (para [0054], teaching wherein "less than 4.2 U/gram" can indicate severe pancreatic disfunction).

As per claim 23, Fallon and Darman teach claim 20 and Fallon further teaches wherein the level of chymotrypsin present in the fecal sample is determined using an enzymatic photospectrometry method (para [0055], "Each stool sample was analyzed using an enzymatic photospectrometry analysis to determine the level of fecal chymotrypsin").

As per claim 24, Fallon and Darman teach claim 20 and Fallon further teaches administering to the patient an effective amount of a pharmaceutical composition comprising one or more digestive enzymes if the patient is diagnosed as having the disorder (para [0025], "administering an effective amount of digestive/pancreatic enzymes to an individual having the disorder in order to improve a symptom of the disorder").

As per claim 25, Fallon and Darman teach claim 24 and Fallon further teaches determining if the administration of the pharmaceutical composition reduces or ameliorates one or more symptoms associated with the neurological or mental health disorder (para [0055], teaching wherein "levels of fecal chymotrypsin" in the patients "was compared to the levels of fecal chymotrypsin" in non-disordered subjects in order to determine if the patient "would benefit from the administration of digestive enzymes").

As per claim 26, Fallon and Darman teach claim 25 and Fallon further teaches comparing the post-administration measurement of one or more symptoms of the disorder to a preadministration measurement of the one or more symptoms of the disorder (para [0045], "Physical symptoms of the disease... were monitored and measured").

As per claim 27, Fallon teaches a method of identifying a patient likely to benefit from administration of a pharmaceutical composition comprising one or more digestive enzymes (para [0024], "determining whether an individual will benefit from the administration of pancreatic/digestive enzymes to treat the... disorder") comprising obtaining a fecal sample from the patient (para [0002], "analyzing a stool sample of an individual"); determining a level of chymotrypsin present in the fecal sample (para [0027], "measuring a quantitative level of a pancreatic enzyme, such as chymotrypsin, present in the stool sample"); and identifying the patient as likely to benefit from administration of the pharmaceutical composition (para [0055], teaching determining if the patient "would benefit from the administration of digestive enzymes") if the determined fecal chymotrypsin level is 8.4 U/gram or less (para [0054], "Normal levels of chymotrypsin are considered be greater than 8.4 U/gram") and the patient is diagnosed with a disorder associated with gastrointestinal dysfunction (para [0037], disclosing wherein "dysautonomic disorders such as Parkinson's disease" can cause "partial paresis of the gastrointestinal tract," which will "preclude the proper formation and/or release of... pancreatic enzymes such as chymotrypsin").

Fallon fails to teach the further claim limitations taught by Darman, namely wherein the disorder is a neurological or mental health disorder selected from the group consisting of bipolar disorder and obsessive compulsive disorder (pg 1 para 4 to pg 2 para 1, teaching wherein "illnesses... considered psychiatric in nature," such as "obsessive compulsive disorder" and "bipolar disorder" can be caused by issues with "the pancreas, in regard to both it's insulin production and digestive enzyme production").

It would have been obvious to one with ordinary skill in the art to treat the disorders taught in Darman with the digestive enzyme formulation taught in Fallon because Darman teaches that "mental illnesses" such as bipolar disorder and OCD, can be affected by problems with the pancreas, especially "in regard to both it's insulin production and digestive enzyme production" (pg 2 para 1); that "gut toxins, and the issues that cause them, can cause severe psychiatric symptoms" (pg 5 para 4); and that mental illnesses such as "bipolar disorder" can be treated by using "digestive enzymes" to "fix the gut... to digest and absorb" properly (pg 8 para 4). Fallon also teaches that the digestive enzyme formulation can be used to "ameliorate dysautonomic symptoms" such as "abnormality of protein digestion and/or pancreatic dysfunction" caused by "partial paresis of the gastrointestinal tract." Using the enzyme formulation to treat the disorders taught in Darman therefore increases the effectiveness and marketability of the product.

As per claim 28, Fallon and Darman teach claim 27 and Fallon further teaches determining if the patient exhibits one or more symptoms of the neurological or mental health disorder (para [0045], "Physical symptoms of the disease... were monitored and measured").

As per claim 29, Fallon and Darman teach claim 27 and Fallon further teaches wherein the benefit comprises a reduction or amelioration of one or more symptoms associated with the disorder (para [0057], "administration of digestive enzymes benefits individuals... by ameliorating the symptoms of the disorder").

As per claim 30, Fallon and Darman teach claim 27 and Fallon further teaches wherein the level of chymotrypsin present in the fecal sample is determined using an enzymatic photospectrometry method (para [0055], "Each stool sample was analyzed using an enzymatic photospectrometry analysis to determine the level of fecal chymotrypsin").

-- Please See Supplemental Box 3 --

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
-- Please See Supplemental Box 2 --

As per claim 31, Fallon and Darman teach claim 27 and Fallon further teaches administering to the patient an effective amount of a pharmaceutical composition comprising one or more digestive enzymes (para [0025], "administering an effective amount of digestive/pancreatic enzymes to an individual having the disorder in order to improve a symptom of the disorder").

As per claim 37, Fallon teaches a pharmaceutical preparation for treating an individual exhibiting one or more symptoms of a disorder (para [0025], "improve a symptom of the disorder") associated with gastrointestinal dysfunction (para [0037], disclosing wherein "dysautonomic disorders such as Parkinson's disease" can cause "partial paresis of the gastrointestinal tract," which will "preclude the proper formation and/or release of... pancreatic enzymes such as chymotrypsin") comprising a therapeutically effective amount of a digestive enzyme (para [0028], "a formulation of digestive enzymes/pancreatic enzymes").

Fallon fails to teach the further claim limitations taught by Darman, namely wherein the disorder is a neurological or mental health disorder selected from the group consisting of bipolar disorder and obsessive compulsive disorder (pg 1 para 4 to pg 2 para 1, teaching wherein "illnesses... considered psychiatric in nature," such as "obsessive compulsive disorder" and "bipolar disorder" can be caused by issues with "the pancreas, in regard to both it's insulin production and digestive enzyme production").

It would have been obvious to one with ordinary skill in the art to treat the disorders taught in Darman with the digestive enzyme formulation taught in Fallon because Darman teaches that "mental illnesses" such as bipolar disorder and OCD, can be affected by problems with the pancreas, especially "in regard to both it's insulin production and digestive enzyme production" (pg 2 para 1); that "gut toxins, and the issues that cause them, can cause severe psychiatric symptoms" (pg 5 para 4); and that mental illnesses such as "bipolar disorder" can be treated by using "digestive enzymes" to "fix the gut... to digest and absorb" properly (pg 8 para 4). Fallon also teaches that the digestive enzyme formulation can be used to "ameliorate dysautonomic symptoms" such as "abnormality of protein digestion and/or pancreatic dysfunction" caused by "partial paresis of the gastrointestinal tract." Using the enzyme formulation to treat the disorders taught in Darman therefore increases the effectiveness and marketability of the product for treating these specific symptoms.

As per claim 38, Fallon and Darman teach claim 37 and Fallon further teaches wherein the digestive enzyme is selected from the group consisting of amylase (para [0038], "therapeutically effective amount of... an amylase"), lipase (para [0038], "therapeutically effective amount of... a lipase"), and protease (para [0038], "therapeutically effective amount of a protease").

As per claim 39, Fallon and Darman teach claim 37 and Fallon further teaches wherein the digestive enzyme is further selected from the group consisting of: chymotrypsin and trypsin (para [0038], "The formulation may include... chymotrypsin, trypsin"), papaya (para [0038], "The formulation may include... papaya") and papain (para [0038], "The formulation may include... papain").

As per claim 40, Fallon and Darman teach claim 37 and Fallon further teaches wherein the enzyme is derived from a source selected from the group consisting of animal enzymes, plant enzymes, and synthetic enzymes (para [0044], "enzymes can be in the form of animal or plant derivatives, natural or synthetic").

As per claim 41, Fallon and Darman teach claim 37 and Fallon further teaches wherein the preparation is manufactured using a technology selected from the group consisting of Prosolv. technology (para [0038], "encapsulated using Prosolv technology"), enteric coating, lipid encapsulation, direct compression, dry granulation, wet granulation, and a combination thereof (para [0038], "encapsulated using enteric coating, lipid encapsulation, direct compression, dry granulation, wet granulation, and/or a combination of these methods").

As per claim 42, Fallon and Darman teach claim 37 and Fallon further teaches wherein the preparation is administered orally via a dosage formulation selected from the group consisting of tablets, capsules and sprinkles (para [0045], "dosages were administered in the form of encapsulated tablets, capsules, and sprinkles").

As per claim 43, Fallon and Darman teach claim 38 and Fallon further teaches wherein the amount of amylase ranges from 10,000 to 60,000 USP units/mg (para [0040], "Amylase, 10,000-70,000 USP units/mg").

As per claim 44, Fallon and Darman teach claim 38 and Fallon further teaches wherein the amount of protease ranges from 10,000 to 70,000 USP units/mg (para [0040], "Protease 10,000-80,000 USP units/mg").

As per claim 45, Fallon and Darman teach claim 38 and Fallon further teaches wherein the amount of lipase ranges from 4,000 to 30,000 USP units/mg (para [0040], "Lipase 4,000-40,000 USP units/mg").

As per claim 46, Fallon and Darman teach claim 39 and Fallon further teaches wherein the amount of pancreatin ranges from 2,000 to 6,000 USP units/mg (para [0040], "Pancreatin 2,000-6,000 USP units/mg").

As per claim 47, Fallon and Darman teach claim 39 and Fallon further teaches wherein the amount of chymotrypsin ranges from 2 to 5 mg (para [0040], "Chymotrypsin 2-5 mg").

As per claim 48, Fallon and Darman teach claim 39 and Fallon further teaches wherein the amount of papain ranges from 3,000 to 10,000 USP units/mg (para [0040], "Papain 3,000-30,000 USP units/mg").

-- Please See Supplemental Box 4 --

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Supplemental Box 3

As per claim 49, Fallon and Darman teach claim 39 and Fallon further teaches wherein the amount of papaya ranges from 30 to 60 mg (para [0040], "Papaya 30-500 mg").

As per claim 50, Fallon and Darman teach claim 39 and Fallon further teaches wherein the amount of trypsin ranges from 60 to 100 mg (para [0040], "Trypsin 60-100 mg").

As per claim 51, Fallon and Darman teach claim 37 and Fallon further teaches wherein a symptom of the disorder is ameliorated (para [0057], "ameliorating the symptoms of the disorder").

As per claim 58, Fallon teaches a method of treating an individual having a disorder (para [0025], "improve a symptom of the disorder") associated with gastrointestinal dysfunction (para [0037], disclosing wherein "dysautonomic disorders such as Parkinson's disease" can cause "partial paresis of the gastrointestinal tract," which will "preclude the proper formation and/or release of... pancreatic enzymes such as chymotrypsin") with a therapeutically effective amount of digestive enzymes (para [0025], "administering an effective amount of digestive/pancreatic enzymes to an individual having the disorder in order to improve a symptom of the disorder") comprising the steps of measuring a level of fecal chymotrypsin in a stool sample of the individual (para [0027], "measuring a quantitative level of a pancreatic enzyme, such as chymotrypsin, present in the stool sample"); comparing the level of fecal chymotrypsin with a normal fecal chymotrypsin level (para [0055], teaching wherein "levels of fecal chymotrypsin" in the patients "was compared to the levels of fecal chymotrypsin" in non-disordered subjects in order to determine if the patient "would benefit from the administration of digestive enzymes"); and administering the digestive enzymes to the individual if the level of fecal chymotrypsin in the individual is less than the normal fecal chymotrypsin level (claim 18, "administering the digestive enzymes to the individual if the level of fecal chymotrypsin in the individual is less than the normal fecal chymotrypsin level").

Fallon fails to teach the further claim limitations taught by Darman, namely wherein the disorder is a neurological or mental health disorder selected from the group consisting of bipolar disorder and obsessive compulsive disorder (pg 1 para 4 to pg 2 para 1, teaching wherein "illnesses... considered psychiatric in nature," such as "obsessive compulsive disorder" and "bipolar disorder" can be caused by issues with "the pancreas, in regard to both it's insulin production and digestive enzyme production").

It would have been obvious to one with ordinary skill in the art to treat the disorders taught in Darman with the digestive enzyme formulation taught in Fallon because Darman teaches that "mental illnesses" such as bipolar disorder and OCD, can be affected by problems with the pancreas, especially "in regard to both it's insulin production and digestive enzyme production" (pg 2 para 1); that "gut toxins, and the issues that cause them, can cause severe psychiatric symptoms" (pg 5 para 4); and that mental illnesses such as "bipolar disorder" can be treated by using "digestive enzymes" to "fix the gut... to digest and absorb" properly (pg 8 para 4). Fallon also teaches that the digestive enzyme formulation can be used to "ameliorate dysautonomic symptoms" such as "abnormality of protein digestion and/or pancreatic dysfunction" caused by "partial paresis of the gastrointestinal tract." Using the enzyme formulation to treat the disorders taught in Darman therefore increases the effectiveness and marketability of the product for treating these mental illnesses.

As per claim 59, Fallon and Darman teach claim 58 and Fallon further teaches the steps of administering the digestive enzymes to the individual in order to promote protein digestion (para [0037], "an improvement of protein digestion"); and administering the digestive enzymes to the individual in order to ameliorate a symptom of the disorder (para [0057], "ameliorating the symptoms of the disorder").

As per claim 60, Fallon and Darman teach claim 58 and Fallon further teaches wherein the stool sample is measured using enzymatic photospectrometry (para [0055], "Each stool sample was analyzed using an enzymatic photospectrometry analysis to determine the level of fecal chymotrypsin").

Claims 13 and 52 lack an inventive step under PCT Article 33(3) as being obvious over Fallon in view of Darman, and in further view of the article titled "Basics of Alzheimer's Disease" by the Alzheimer's Association (hereinafter "The Alzheimer's Article")

As per claim 13, Fallon and Darman teach claim 2 and Fallon further teaches wherein the disorder is a neurodegenerative disorder (para [0016]).

Fallon and Darman fail to teach the further claim limitation taught by The Alzheimer's Article, namely wherein the neurodegenerative disorder is Alzheimer's disease (pg 2 para 1, "Alzheimer's is a disease of the brain") and wherein the one or more symptoms of Alzheimer's is selected from the group consisting of: memory loss (pg 6 col 2 para 1), language deterioration (pg 6 col 2 para 5), poor judgment (pg 7 col 1 para 3), confusion (pg 7 col 1 para 1), mood swings (col 7 ln 2 para 3), and a combination thereof.

It would have been obvious to one with ordinary skill in the arts to use the symptoms taught in The Alzheimer's Article within the treatment method taught in Fallon and Darman because these symptoms would be well known to one with ordinary skill in the art, and the use of these symptoms would greatly increase the accuracy and effectiveness of the treatment, thereby increasing the marketability of the product for treating Alzheimer's.

-- Please See Supplemental Box 5 --

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Supplemental Box 4

As per claim 52, Fallon and Darman teach claim 51 and Fallon further teaches wherein the disorder is a neurodegenerative disorder (para [0016]).

Fallon and Darman but fail to teach the further claim limitation taught by The Alzheimer's Article, namely wherein the neurodegenerative disorder is Alzheimer's disease (pg 2 para 1, "Alzheimer's is a disease of thebrain") and wherein the symptoms of Alzheimer's are selected from the group consisting of: memory loss (pg 6 col 2 para 1), language deterioration (pg 6 col 2 para 5), poor judgment (pg 7 col 1 para 3), confusion (pg col 1 para 1), mood swings (pg 7 col 2 para 3), and a combination thereof.

It would have been obvious to one with ordinary skill in the arts to use the symptoms taught in The Alzheimer's Article within the treatment method taught in Fallon and Darman because these symptoms would be well known to one with ordinary skill in the art, and the use of these symptoms would greatly increase the accuracy and effectiveness of the treatment, thereby increasing the marketability of the product for treating Alzheimer's.

Claims 14-15 and 53-54 lack an inventive step under PCT Article 33(3) as being obvious over Fallon in view of Darman, and in further view of the article titled "Bipolar disorder" by Mayo Clinic staff (hereinafter "The Bipolar Article")

As per claim 14, Fallon and Darman teach claim 2 and Darman further teaches wherein the disorder is a bipolar disorder (pg 1 para 4 to pg 2 para 1, teaching wherein "illnesses... considered psychiatric in nature," such as "bipolar disorder" can be caused by issues with "the pancreas, in regard to both it's insulin production and digestive enzyme production").

Fallon and Darmon fail to teach the further claim limitations taught by The Bipolar Article, namely wherein the the bipolar syndrome is the manic phase of bipolar syndrome (pg 1 para 3, "Bipolar disorder symptoms are characterized by an alternating pattern of emotional highs/mania and lows/depression"), and wherein the one or more symptoms of the manic bipolar disorder is selected from the group consisting of (pg 2 para 1): euphoria, extreme optimism, inflated self esteem, poor judgment, rapid speech, racing thoughts, aggressive behavior, agitation, increased physical activity, risky behavior, spending sprees, increased drive to perform or achieve goals, increased sexual drive, decreased need for sleep, tendency to be easily distracted, inability to concentrate, drug abuse, and a combination thereof.

It would have been obvious to one with ordinary skill in the arts to use the symptoms taught in The Bipolar Article within the treatment method taught in Fallon and Darman because these symptoms would be well known to one with ordinary skill in the art, and the use of these symptoms would greatly increase the accuracy and effectiveness of the treatment, thereby increasing the marketability of the product for treating these specific symptoms.

As per claim 15, Fallon and Darman teach claim 2 and Darman further teaches wherein the disorder is a bipolar disorder (pg 1 para 4 to pg 2 para 1, teaching wherein "illnesses... considered psychiatric in nature," such as "bipolar disorder" can be caused by issues with "the pancreas, in regard to both it's insulin production and digestive enzyme production").

Fallon and Darmon fail to teach the further claim limitations taught by The Bipolar Article article, namely wherein the the bipolar syndrome is the depressive phase of bipolar syndrome (pg 1 para 3, "Bipolar disorder symptoms are characterized by an alternating pattern of emotional highs/mania and lows/depression"), and wherein the one or more symptoms of the depressive bipolar disorder is selected from the group consisting of (pg 2 para 2 to pg 3 para 1): sadness, hopelessness, suicidal thoughts or behavior, anxiety, guilt, sleep problems, appetite problems, fatigue, loss of interest in daily activities, problems concentrating, irritability, chronic pain without a known cause, and a combination thereof.

It would have been obvious to one with ordinary skill in the arts to use the symptoms taught in The Bipolar Article within the treatment method taught in Fallon and Darman because these symptoms would be well known to one with ordinary skill in the art, and the use of these symptoms would greatly increase the accuracy and effectiveness of the treatment, thereby increasing the marketability of the product for treating these specific symptoms.

As per claim 53, Fallon and Darman teach claim 51 and Darman further teaches wherein the disorder is a bipolar disorder (pg 1 para 4 to pg 2 para 1, teaching wherein "illnesses... considered psychiatric in nature," such as "bipolar disorder" can be caused by issues with "the pancreas, in regard to both it's insulin production and digestive enzyme production").

Fallon and Darmon fail to teach the further claim limitations taught by The Bipolar Article, namely wherein the the bipolar syndrome is the manic phase of bipolar syndrome (pg 1 para 3, "Bipolar disorder symptoms are characterized by an alternating pattern of emotional highs/mania and lows/depression"), and wherein the one or more symptoms of the manic bipolar disorder is selected from the group consisting of (pg 2 para 1): euphoria, extreme optimism, inflated selfesteem, poor judgment, rapid speech, racing thoughts, aggressive behavior, agitation, increased physical activity, risky behavior, spending sprees, increased drive to perform or achieve goals, increased sexual drive, decreased need for sleep, tendency to be easily distracted, inability to concentrate, drug abuse, and a combination thereof.

It would have been obvious to one with ordinary skill in the arts to use the symptoms taught in The Bipolar Article within the treatment method taught in Fallon and Darman because these symptoms would be well known to one with ordinary skill in the art, and the use of these symptoms would greatly increase the accuracy and effectiveness of the treatment, thereby increasing the marketability of the product for treating these specific symptoms.

-- Please See Supplemental Box 6 --

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
-- Please See Supplemental Box 5 --

As per claim 54, Fallon and Darman teach claim 51 and Darman further teaches wherein the disorder is a bipolar disorder (pg 1 para 4 to pg 2 para 1, teaching wherein "illnesses... considered psychiatric in nature," such as "bipolar disorder" can be caused by issues with "the pancreas, in regard to both it's insulin production and digestive enzyme production").

Fallon and Darmon fail to teach the further claim limitations taught by The Bipolar Article, namely wherein the the bipolar syndrome is the depressive phase of bipolar syndrome (pg 1 para 3, "Bipolar disorder symptoms are characterized by an alternating pattern of emotional highs/mania and lows/depression"), and wherein the one or more symptoms of the depressive bipolar disorder is selected from the group consisting of (pg 2 para 2 to pg 3 para 1): sadness, hopelessness, suicidal thoughts or behavior, anxiety, guilt, sleep problems, appetite problems, fatigue, loss of interest in daily activities, problems concentrating, irritability, chronic pain without a known cause, and a combination thereof.

It would have been obvious to one with ordinary skill in the arts to use the symptoms taught in The Bipolar Article within the treatment method taught in Fallon and Darman because these symptoms would be well known to one with ordinary skill in the art, and the use of these symptoms would greatly increase the accuracy and effectiveness of the treatment, thereby increasing the marketability of the product for treating these specific symptoms.

Claims 16-17 and 55-56 lack an inventive step under PCT Article 33(3) as being obvious over Fallon in view of Darman, and in further view of the article titled "Obsessive-compulsive disorder" By Mayo Clinic staff (hereinafter "The OCD Article")

As per claim 16, Fallon and Darman teach claim 2 and Darman further teaches wherein the disorder is obsessive compulsive disorder (pg 1 para 4 to pg 2 para 1, teaching wherein "illnesses... considered psychiatric in nature," such as "obsessive compulsive disorder" can be caused by issues with "the pancreas, in regard to both it's insulin production and digestive enzyme production").

Fallon and Darmon fail to teach the further claim limitations taught by The OCD Article, namely wherein the one or more symptoms of OCD involving obsessions is selected from the group consisting of (pg 2 para 2): fear of being contaminated by shaking hands or by touching objects others have touched, doubts that the individual has locked the door or turned off the stove, repeated thoughts that the individual has hurt someone in a traffic accident, intense distress when objects are not orderly, lined up properly or facing the right way, images of hurting the individual's child, impulses to shout obscenities in inappropriate situations, avoidance of situations that can trigger obsessions, such as shaking hands, replaying pornographic images in the individual's mind, dermatitis because of frequent hand washing, skin lesions because of picking at the skin, hair loss or bald spots because of hair pulling, and a combination thereof.

It would have been obvious to one with ordinary skill in the arts to use the symptoms taught in The OCD Article within the treatment method taught in Fallon and Darman because these symptoms would be well known to one with ordinary skill in the art, and the use of these symptoms would greatly increase the accuracy and effectiveness of the treatment, thereby increasing the marketability of the product for treating these specific symptoms.

As per claim 17, Fallon and Darman teach claim 2 and Darman further teaches wherein the disorder is obsessive compulsive disorder (pg 1 para 4 to pg 2 para 1, teaching wherein "illnesses... considered psychiatric in nature," such as "obsessive compulsive disorder" can be caused by issues with "the pancreas, in regard to both it's insulin production and digestive enzyme production").

Fallon and Darmon fail to teach the further claim limitations taught by The OCD Article, namely wherein the one or more symptoms of OCD involving compulsions is selected from the group consisting of (pg 2 para 5 to pg 3 para 1): washing hands until the skin becomes raw, checking doors repeatedly to make sure they are locked, checking the stove repeatedly to make sure it is off, counting in certain patterns, and a combination thererof.

It would have been obvious to one with ordinary skill in the arts to use the symptoms taught in The OCD Article within the treatment method taught in Fallon and Darman because these symptoms would be well known to one with ordinary skill in the art, and the use of these symptoms would greatly increase the accuracy and effectiveness of the treatment, thereby increasing the marketability of the product for treating these specific symptoms.

As per claim 55, Fallon and Darman teach claim 51 and Darman further teaches wherein the disorder is obsessive compulsive disorder (pg 1 para 4 to pg 2 para 1, teaching wherein "illnesses... considered psychiatric in nature," such as "obsessive compulsive disorder" can be caused by issues with "the pancreas, in regard to both it's insulin production and digestive enzyme production").

Fallon and Darmon fail to teach the further claim limitations taught by The OCD Article, namely wherein the symptom of OCD involving obsessions is selected from the group consisting of (pg 2 para 2): fear of being contaminated by shaking hands or by touching objects others have touched, doubts that the individual has locked the door or turned off the stove, repeated thoughts that the individual has hurt someone in a traffic accident, intense distress when objects are not orderly, lined up properly or facing the right way, images of hurting the individual's child, impulses to shout obscenities in inappropriate situations, avoidance of situations that can trigger obsessions, such as shaking hands, replaying pornographic images in the individual's mind, dermatitis because of frequent hand washing, skin lesions because of picking at the skin, hair loss or bald spots because of hair pulling, and a combination thereof.

It would have been obvious to one with ordinary skill in the arts to use the symptoms taught in The OCD Article within the treatment method taught in Fallon and Darman because these symptoms would be well known to one with ordinary skill in the art, and the use of these symptoms would greatly increase the accuracy and effectiveness of the treatment, thereby increasing the marketability of the product for treating these specific symptoms.

-- Please See Supplemental Box 7 --

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**

Continuation of:
Supplemental Box 6

As per claim 56, Fallon and Darman teach claim 51 and Darman further teaches wherein the disorder is obsessive compulsive disorder (pg 1 para 4 to pg 2 para 1, teaching wherein "illnesses... considered psychiatric in nature," such as "obsessive compulsive disorder" can be caused by issues with "the pancreas, in regard to both it's insulin production and digestive enzyme production").
Fallon and Darmon fail to teach the further claim limitations taught by The OCD Article, namely wherein the symptom of OCD involving compulsions is selected from the group consisting of (pg 2 para 5 to pg 3 para 1): washing hands until the skin becomes raw, checking doors repeatedly to make sure they are locked, checking the stove repeatedly to make sure it is off, counting in certain patterns, and a combination thereof.

It would have been obvious to one with ordinary skill in the arts to use the symptoms taught in The OCD Article within the treatment method taught in Fallon and Darman because these symptoms would be well known to one with ordinary skill in the art, and the use of these symptoms would greatly increase the accuracy and effectiveness of the treatment, thereby increasing the marketability of the product for treating these specific symptoms.

Claims 18 and 57 lack an inventive step under PCT Article 33(3) as being obvious over Fallon in view of Darman, and in further view of the article titled "Oppositional defiant disorder" By Mayo Clinic staff (hereinafter "The ODD Article")

As per claim 18, Fallon and Darman teach claim 2 but fail to teach the further claim limitation taught by The ODD Article, namely wherein the disorder is Oppositional defiant disorder (pg 3 para 1, teaching "Oppositional defiant disorder" to be a "behavioral or mental health problem") and wherein the one or more symptoms of ODD is selected from the group consisting of (pg 2 para 3): losing one's temper; arguing with adults; actively defying requests; refusing to follow rules; deliberately annoying other people; blaming others for one's own mistakes or misbehavior; being touchy, easily annoyed or angered, resentful, spiteful, or vindictive, and a combination thereof.
It would have been obvious to one with ordinary skill in the arts to use the symptoms taught in The OCD Article within the treatment method taught in Fallon and Darman because these symptoms would be well known to one with ordinary skill in the art, and the use of these symptoms would greatly increase the accuracy and effectiveness of the treatment, thereby increasing the marketability of the product for treating these specific symptoms.

As per claim 57, Fallon and Darman teach claim 51 but fail to teach the further claim limitation taught by The ODD Article, namely wherein the disorder is Oppositional defiant disorder (pg 3 para 1, teaching "Oppositional defiant disorder" to be a "behavioral or mental health problem") and wherein the ODD symptom is selected from the group consisting of (pg 2 para 3): losing one's temper; arguing with adults; actively defying requests; refusing to follow rules; deliberately annoying other people; blaming others for one's own mistakes or misbehavior; being touchy, easily annoyed or angered, resentful, spiteful, or vindictive, and a combination thereof.

It would have been obvious to one with ordinary skill in the arts to use the symptoms taught in The OCD Article within the treatment method taught in Fallon and Darman because these symptoms would be well known to one with ordinary skill in the art, and the use of these symptoms would greatly increase the accuracy and effectiveness of the treatment, thereby increasing the marketability of the product for treating these specific symptoms.

Claims 1-60 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry